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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/019,822	08/21/2002	Vincent E. Manetta	P22,901-A USA	9998

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EXAMINER

GOLLAMUDI, SHARMILA S

ART UNIT                PAPER NUMBER

1616

DATE MAILED: 09/01/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	10/019,822	MANETTA ET AL.	
	<b>Examiner</b>	<b>Art Unit</b>	
	Sharmila S. Gollamudi	1616	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

**A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.**

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
  - If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
  - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
  - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) Responsive to communication(s) filed on 21 August 2002.
- 2a) This action is FINAL.                    2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) Claim(s) 1-38 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) Claim(s) \_\_\_\_\_ is/are allowed.
- 6) Claim(s) 1-38 is/are rejected.
- 7) Claim(s) \_\_\_\_\_ is/are objected to.
- 8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.  
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
  - a) All
  - b) Some \*
  - c) None of:
    1. Certified copies of the priority documents have been received.
    2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
    3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)                     |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | Paper No(s)/Mail Date. _____.   |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____. | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
|  | 6) <input type="checkbox"/> Other: _____.                                   |

## **DETAILED ACTION**

Receipt of Preliminary Amendments to Specification received on August 21, 2002 is acknowledged. Claims 1-38 are pending in this application.

### ***Information Disclosure Statement***

The information disclosure statement (IDS) submitted on 6/16/03 has been considered by the examiner. The information disclosure statement filed 8/5/02 fails to comply with 37 CFR 1.98(a)(2), which requires a legible copy of each U.S. and foreign patent; each publication or that portion which caused it to be listed; and all other information or that portion which caused it to be listed. Page 6 of the IDS has not been considered since copies of each non-patent literature have not been submitted. It has been placed in the application file, but the information referred to therein has not been considered.

### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

**Claims 1-17 and 36-38 are rejected under 35 U.S.C. 102(b) as being anticipated by WO 99/02133 to Lefevre et al.**

Lefevre discloses a topical application of a combination of benzoyl peroxide and a second active ingredient in a multicompartiment dispensing system. The dispensing system contains a first composition of benzoyl peroxide and a second active ingredient selected from an antifungal agent or an antimicrobial agent. See abstract.

The first and second composition generate a final composition that is mixed upon delivery. See page 2, lines 20-30. The preferred second active agent is erythromycin, natamycin, clindamycin, or linocomycin. See page 3, lines 19-25. The ratio of the two active agents may be adjusted between the range of 1:1 to 1:50 and preferably 1:2 to 1:20. See page 4, lines 34-38. The concentration of the benzoyl peroxide is between 2-15% and the amount of erythromycin is up to 30%. See page 5. Viscosity agents for gelling disclosed are Carbopol 940 and hydroxypropylmethylcellulose and additional viscosity agents are Carbopol Ultrez, xanthan, and carrageenans. The solvents disclosed are ethanol, polyethylene glycol, propylene glycol, and glycerol. See page 4.

More specifically, in an preferred embodiment, the first composition contains 5% benzoyl peroxide suspended in an aqueous suspension adjusted with sodium hydroxide to a pH of 8 and Carbopol 940 (viscosifying agent) with a viscosity of 500-5000cps. The second composition contains 30% erythromycin dissolved in 96% ethanol and Carbopol Ultrez. The viscosity of the erythromycin composition is comparable to the viscosity of the benzoyl peroxide gel. The final composition yields an end concentration of 3% erythromycin and 5% benzoyl peroxide. See page 6, lines 9-30 and example 1.

Lastly, Lefevre states that a dispensing system that allows for separate containment as well as simultaneous dosing is preferred. The disclosure of WO 97/27841 in regards to the dispensing system is incorporated in to Lefevre. See page, lines 10-18.

WO 97 discloses one pair of plastic pouches wherein the outlets for the pouches are close together and discharge the contents upon the tearing of the opening at the end of the pouch. See

page 9, lines 27-32. Additionally, WO 97 discloses the use of non-translucent packaging material with very low oxygen permeation rates, i.e. alumina-coated polymers. See page 8, lines 25-35.

**Claims 1-7 are rejected under 35 U.S.C. 102(b) as being anticipated WO 93/15726 to Baroody et al.**

Baroody et al disclose a composition for the treatment of acne containing clindamycin in a concentration of 0.2-4%, preferably 1-2% and 1-20% benzoyl peroxide, preferably 2.5-10%. See abstract and claim 1. The topical composition is maintained in two separately maintained packages. The package may be vials, ampules, pouches, jars, etc. see page 9. The benzoyl peroxide is present in a stable aqueous gel suspension wherein the gelling agent has a relatively low viscosity at the storage pH of 3.5-7. The clindamycin is in a solution with an adjusted pH of 3.5-7. see page 4, lines 1-20. This low viscosity of the first solution allows both the first and second solution to be easily combined to product a high viscosity gel. See page 5, lines 1-3. the gelling agent is a carboxylated polymer, i.e. Carbopol. See examples. Table 1 on page 7 provides the preferred ranges of the components. Example 1 teaches a 5:1 ratio of benzoyl peroxide to clindamycin.

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

- (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

**Claims 18-24 and 26-28 are rejected under 35 U.S.C. 103(a) as being unpatentable over WO 99/02133 to Lefevre et al in view of US patent 5,350,769 to Kasai et al.**

As set forth above, Lefevre discloses a topical application of a combination of benzoyl peroxide and a second active ingredient in a multicompartiment dispensing system. The dispensing system contains a first composition of benzoyl peroxide and a second active ingredient selected from an antifungal agent or an antimicrobial agent. See abstract. The ratio of the two active agents may be adjusted between the range of 1:1 to 1:50 and preferably 1:2 to 1:20. See page 4, lines 34-38. The concentration of the benzoyl peroxide is between 2-15% and the amount of erythromycin is up to 30%. See page 5. Viscosity agents for gelling disclosed are Carbopol 940 and cellulose derivatives such as hydroxypropylmethyl cellulose and additional viscosity agents are Carbopol Ultrez, xanthan, and carrageenans in a range of 0.1-3%. The solvents disclosed are ethanol, polyethylene glycol, propylene glycol, and glycerol. See page 4. The gelling agents have a viscosity range of 100-30,000 cps.

Although Lefevre et al teach the use of cellulose derivatives, the reference does not specify the instant derivative, hydroxypropylmethyl cellulose.

Kasai et al teach an anti-inflammatory gel containing a nonionic polymer. Kasai teaches instant hydroxypropyl cellulose, hydroxypropylmethyl cellulose, hydroxymethyl cellulose, and the like are all capable of forming a gel structure in the amount of 0.5-20%. See column 2, lines 5-32.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to combine the teachings of Lefevre et al and Kasai et al and utilize the instant cellulose derivative. One would have been motivated to do so with the expectation of similar results since Kasai teaches the functional equivalency of the instant cellulose derivative and Lefevre's hydroxypropylmethyl cellulose. Therefore, it is *prima facie* obvious to substitute one equivalent component with another since the prior art establishes that both hydroxypropyl cellulose and hydroxypropylmethyl cellulose both function the same and are utilized for the same purpose.

**Claims 25 and 29-35 are rejected under 35 U.S.C. 103(a) as being unpatentable over WO 99/02133 to Lefevre et al in view of US patent 5,350,769 to Kasai et al in further view of US patent 4,692,329 to Klein et al.**

As set forth above, Lefevre discloses a topical application of a combination of benzoyl peroxide and a second active ingredient in a multicompartiment dispensing system. Kasai et al teach the functional equivalency of hydroxypropyl cellulose and hydroxypropylmethyl cellulose in a topical composition.

The references do not teach the use of instant surfactant, dioctyl sodium sulfosuccinate.

Klein et al discloses a erythromycin and benzoyl peroxide composition, wherein the actives may be packaged separately. Klein et al teach the use of dioctyl sodium sulfosuccinate to

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provide stability to the peroxide component in the formulation. Further, the sulfosuccinate allows evaporation and uniform release of the peroxide compound so as to avoid burning and erythema.

See column 3, lines 14-25. Klein also teaches the use of various gelling agents such as Example 13 discloses a gel formulation containing 5.46% benzoyl peroxide, 2% erythromycin, 44.10% ethanol, 6% polyoxyethylene lauryl ether, 2.50 colloidal magnesium aluminum (gelling agent), 1% hydroxymethylcellulose, 0.02% dioctyl sodium sulfosuccinate, and water. Sodium hydroxide and use of Carbopol as the gelling agent is taught in examples 11-12.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to combine the teachings of the references above and further utilize the instant surfactant. One would have been motivated to do so since Klein teaches dioctyl sodium sulfosuccinate not only provides stability to a composition that contains both erythromycin and benzoyl peroxide but it also allows for the uniform release of the peroxide compound so as to avoid burning and erythema upon application. Therefore, one would be motivated to utilize the instant surfactant to increase stability and to avoid the side effects caused by the use of peroxides topically.

### *Conclusion*

No claims are allowed at this time.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sharmila S. Gollamudi whose telephone number is 571-272-0614. The examiner can normally be reached on M-F (8:00-5:30), alternate Fridays off.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Kunz can be reached on 571-272-0887. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Sharmila S. Gollamudi  
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Art Unit 1616

SSG

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